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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,505	02/14/2005	Hisashi Narimatsu	BJS-159-86	3424

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EXAMINER	
PROUTY, REBECCA E	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,505	NARIMATSU ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,9,11-14,16,17 and 22-26* is/are pending in the application.

4a) Of the above claim(s) *22 and 23* is/are withdrawn from consideration.

5)☒ Claim(s) *6,11 and 12* is/are allowed.

6)☒ Claim(s) *7,9,13,14,16,17 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-5, 8, 10, 15, and 18-21 have been canceled. Claims 6, 7, 9, 11-14, 16, 17, 22, 23 and newly presented claims 24-26 are still at issue and are present for examination.

Applicants' arguments filed on 2/22/08, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 22 and 23 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/29/07.

Claims 7, 9, 13, 14, 16, 17 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 13, and 26 (upon which claims 9, 14, 16, and 17 depend) are indefinite in the recitation of “high stringency conditions” as the specification does not define what conditions constitute “high stringency”. While pages 18-19 of the specification describes some conditions which are intended to be

high stringency, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NO: 4, a sequence must be to be included within the scope of these claims.

Claim 9 is indefinite in the recitation of "a nucleotide sequence represented by of SEQ ID NO:4" as it is unclear if "represented by" or "of" was intended. If "represented by" was intended it is unclear if this is synonymous with "a nucleotide sequence comprising SEQ ID NO:4" or if SEQ ID NO:4 is just one representative member of a larger undefined group of sequences. For purposes of further examination it is assumed applicants intended to delete "represented by" and thus the claim should read "The nucleic acid of Claim 7 having a nucleotide sequence of SEQ ID NO:4".

Claim 13 is indefinite in the recitation of "wherein the nucleic acid contains 18 bases to 26 bases" as nucleic acids are made up of nucleotides not bases.

Claim 14 is confusing in the recitation of "A primer comprising the analytical nucleic acid of Claim 13 selected from a group consisting of …" as it is unclear if it is the primer or

the analytical nucleic acid which much be part of the recited group. Furthermore, the claim is grammatically improper in the use of the indefinite article "a" instead of the definite article "the" prior to "group consisting of". For purposes of further examination it is assumed that it is the analytical nucleic acid which much be part of the recited group.

Claim 26 is confusing in the use of the phrase "completely hybridizes" as it is unclear how a nucleic acid could "partially hybridize". Either a nucleic acid hybridizes to another nucleic acid under specific conditions or it doesn't.

Claims 13, 14, 16, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 13 (upon which claims 14, 16, and 17 depend) recites "wherein the nucleic acid contains 18 bases to 26 bases" however the specification as originally filed fails to provide support for fragments of specifically this length.

Claims 13, 14, 16, 17, and 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while

being enabling for nucleic acids encoding the protein of SEQ ID NO:3 and the nucleic acids consisting of fragments of SEQ ID NO:4 of 18-26 nucleotides, does not reasonably provide enablement for any nucleic acid encoding a protein having 90% or 95% identity to SEQ ID NO:3 or any nucleic acid which will hybridize to SEQ ID NO:4 (or any nucleic acid encoding a protein having 90% or 95% identity to SEQ ID NO:3) under high stringency conditions or for any nucleic acid comprising a fragment thereof of 18-26 nucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

Applicants response appears to indicate that they believe the amendments to the claims obviate the instant rejection. However, while claims 6, 7, 9, 11, and 12 were amended to recite nucleic acids of a scope commensurate with the enabled invention claims 13, 14, 16, and 17 were amended to recite a scope of nucleic acids which clearly exceeds the enabled invention as clearly not all nucleic acids which comprise a fragment of SEQ ID NO:4 of 18-26 nucleotides will be useful as a diagnostic probe for the levels of SEQ ID NO:4 present in a biological sample as the presence or absence of additional sequences will

alter the hybridization properties to SEQ ID NO:4 unpredictably. Furthermore, nucleic acids which include 18-26 bases of other sequences which encode SEQ ID NO:3 or variants thereof as claimed will also not be useful as claimed as they will not necessarily hybridize to SEQ ID NO:4 at all. Similarly, new claims 24-26 are not fully enabled as the specification clearly does not teach how to use the full scope of nucleic acids claimed as it is well established that high structural identity of a nucleic acid in no way provides any assurance of functional identity. Many nucleic acids within the scope of these claims will not encode a protein having ß-1,4 N-acetylgalactosamine transferase activity and thus cannot be used as taught by the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Isogai et al. (EP 1308459).

Isogai et al. teach a nucleic acid (SEQ ID NO : 1696 of Isogai et al.) having 99.7% identity to residues 72-2060 of SEQ ID NO:4 of the instant application. This nucleic acid will clearly hybridize to SEQ ID NO:4 under even high stringency conditions and comprises fragments of SEQ ID NO:4 of 18-26 nucleotides.

Claims 16 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Isogai et al. (US Patent 6,943,241).

Isogai et al. teach a nucleic acid (SEQ ID NO : 1696 of Isogai et al.) having 99.7% identity to residues 72-2060 of SEQ ID NO:4 of the instant application. This nucleic acid will clearly hybridize to SEQ ID NO:4 under even high stringency conditions and comprises fragments of SEQ ID NO:4 of 18-26 nucleotides.

Claims 16 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Mao et al. (WO 01/72832).

Mao et al. teach a nucleic acid (SEQ ID NO:1 of Mao et al.) having 99.6% identity to residues 1268-1781 of SEQ ID NO:4 of the instant application. This nucleic acid will clearly hybridize to SEQ ID NO:4 under even high stringency conditions and comprises fragments of SEQ ID NO:4 of 18-26 nucleotides.

Claims 14, 16 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. AK097681.

GenBank Accession No. AK097681 teach a nucleic acid having 100% identity to residues 1616-2997 of SEQ ID NO:4 (including all of SEQ ID NO:23) of the instant application. This nucleic acid will clearly hybridize to SEQ ID NO:4 under even high stringency conditions.

Claims 14, 16, 17, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Rees et al. (WO 01/53524).

Rees et al. teach a nucleic acid comprising a sequence having 100% identity to residues 2240-2645 of SEQ ID NO:4 including all of SEQ ID NO:23 (i.e., SEQ ID NO:25 of Rees et al.), and fragments of this nucleic acid for use as a cancer marker and kits comprising fragments of this nucleic acid. This nucleic acid will clearly hybridize to SEQ ID NO:4 under even high stringency conditions.

Claims 14, 16, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Isogai et al. (US Patent 7,193,069).

Isogai et al. teach a nucleic acid comprising a sequence having 100% identity to residues 1851-2997 of SEQ ID NO:4 including all of SEQ ID NO:23 (i.e., SEQ ID NO:2080 of Isogai et al.), and fragments of this nucleic acid for use as a

hybridization probe. This nucleic acid will clearly hybridize to SEQ ID NO:4 under even high stringency conditions.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of Isogai et al. (EP 1308459), Isogai et al. (US Patent 6,943,241), Mao et al. (WO 01/72832), Rees et al. (WO 01/53524) or Isogai et al. (US Patent 7,193,069).

Each of the above references teaches a nucleic acid will clearly hybridize to SEQ ID NO:4 under even high stringency conditions as well as the production of fragments of the disclosed nucleic acid for use as hybridization probes and/or PCR primers. The references do not specifically disclose

fragments of 18-26 nucleotides in length. However, one of ordinary skill in the art would have understood that 20-25 nucleotides in length is the preferred length of nucleotide fragments for use as hybridization probes and/or PCR primers as these lengths are sufficient to provide for uniqueness with even large genomic libraries and to hybridize under the conditions of stringent hybridizations and PCR yet small enough to be easily synthesized and used. As such it would have been obvious to one of ordinary skill in the art make fragments of the disclosed nucleic acids of each of the cited references of 20-25 nucleotides in length.

Claims 6, 11, and 12 are allowed. Claims 7 and 9 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS

of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652